

## **PUBLIC COMMENTS**

### **Interim Final Rule - Chemical Weapons Convention Regulations – Public Comments**

**Published December 30, 1999**

**64 FR 73744**

<b>Company</b>	<b>Date Received</b>
CWCR 1 Proctor & Gamble	January 31, 2000
CWCR 2 The Goodyear Tire & Rubber Company	January 31, 2000
CWCR 3 Chemical Manufacturers Association	January 31, 2000
CWCR 4 Synthetic Organic Chemical Manufacturers Association, Inc, SOCMA	January 31, 2000

# Procter & Gamble

*The Procter & Gamble Company  
Ivorydale Technical Center  
5299 Spring Grove Avenue, Cincinnati, Ohio 45217-1087*

January 31, 2000

Regulatory Policy Division  
Office of Exporter Services  
Bureau of Export Administration  
Room 2705  
14<sup>th</sup> Street and Pennsylvania Avenue, N.W.  
Washington, D.C. 20230

Re: Chemical Weapons Convention Regulations [Interim Rule and Request for Comments]  
(Docket No. 990611158-9311-02)

Dear Sir or Madam:

This presents comments from The Procter and Gamble Company regarding the above cited Chemical Weapons Convention Regulation Interim Rule published on December 30, 1999 [FR Vol. 64, No. 250, pp.73743-73811]. Procter and Gamble is a manufacturer of consumer products including home and personal care products, foods, and cosmetics.

Procter and Gamble supports the Bureau of Export Administration's continuing efforts to develop and finalize the regulations necessary to implement the Chemical Weapons Convention (CWC) in the United States and appreciates this opportunity to comment on the Interim Rule.

## **Impact of the CWC Interim Rule on Consumer Product Facilities**

In this notice, the Bureau of Export Affairs (BXA) specifically requests public comment [p. 73751] on how the Interim Rule would impact facilities that produce unscheduled discrete organic chemicals (UDOCs) solely as consumer goods packaged for retail.

Procter & Gamble supports the exemption in the Interim Rule exemption for facilities that produce UDOCs in the manufacture of food products intended for both humans and animals. It is our belief that a coffee roasting facility poses no threat to the object and purpose of the CWC.

Procter & Gambles believes there are other consumer product facilities that similarly pose no threat to the object and purpose of the CWC that merit strong consideration for exemption from CWC reporting and inspection requirements. These include facilities that 1) process "edible" oils and edible oil byproducts solely for use in packaged consumer goods other than those intended for consumption by humans or animals, 2) produce detergents solely for packaged consumer goods, 3) conduct acid-base reactions as part of normal consumer product formulation.



### Facilities Making Consumer Products Comprised of Processed Edible Oils

Many consumer products including soaps, shampoos, detergents and consumer personal care products are comprised of raw materials derived from edible oils. Edible oils are oils derived from processing grains or other cultivated products including but not limited to soybean oil, corn oil, sunflower oil, palm oil, peanut oil, and olive oil. Edible oils are not singular chemical entities but are complex mixtures of many compounds. For example, a typical lot of sunflower oil is comprised of at least 20 to 40 different hydrocarbons of varying chain lengths (C8 to C22) having varying degrees of saturation (number of carbon/carbon double bonds). Generally, no single molecular entity comprises more than 40% of the mixture and as many as 10 different molecular entities may be present at levels greater than 1%. The relative distribution of individual components in the oil varies by lot. In this way edible oils can be likened to be another type of "crude" oil.

Consumer products manufacturers traditionally do not need to separate or purify the components of these oils for consumer product use because chemical functionality is more important to product performance than chain length. As a result, the distribution of components in each individual batch of oil may not even need to be analyzed. These complex mixtures are usually used as-is in consumer products or are first processed using one of several basic industrial operations to hydrogenate the oils (to reduce the relative number of carbon double bonds) or sulfonate the oils (to produce surface active agents [surfactants]). Hydrogenated and sulfonated edible oils are the building blocks for many consumer products including surface cleaners, detergents and personal care products such as toothpaste, soaps, and shampoos.

The CWC interim rule currently can force facilities that conduct edible oil processing operations in-house solely for the purpose of use in consumer products to alter existing manufacturing operations in order to be able to quantify and document the extent of reaction for CWC purposes. Lot to lot variability can affect the extent of reaction. For example, a manufacturer will now have to conduct analyses both before and after hydrogenation of sunflower oil in order to calculate how much was unsaturated oil was present both beforehand and afterward in order to estimate how much new product was synthesized. This is further complicated if the reaction is continuous. The extra analyses would require additional personnel, equipment and time.

We believe basic processing of edible oils operations is not consistent with that with the intent and purposes of the Chemical Weapons Convention. Edible oils are not discrete chemical entities and trying to "force-fit" them into the definition of UDOCs per the Chemical Weapons Convention creates additional workplace burdens on facility personnel and forces changes in plant equipment and operations in order to comply.

From a purely technical perspective, it is our firm conclusion that an edible oil is not a discrete compound. However, since the CWC definition of UDOCs appears established, it is our recommendation that that facilities that solely conduct synthesis operations with edible oils and edible oil derivatives exclusively for use in packaged consumer products should be exempt from CWC reporting and inspection requirements. The processing operations needed to convert edible oils to raw materials for consumer products are designed to handle large volumes of impure, non-discrete mixtures in relatively simple chemical operations. These kinds of operations are not consistent with the scope or purposes of the CWC.

### Facilities Making Detergents

Detergents are a consumer product that use edible oils and processed edible oils as raw materials. Detergents are an example where the chemical processing occurs in the same operation that produces the finished product for packaging to the consumer. The reaction is continuous and in dedicated equipment developed solely to produce the consumer product.

### Facilities Conducting Acid-Base Reactions During Consumer Product Formulation

The vast majority of consumer products employ acid-base chemistry as an essential part of product formulation. Consumer product formulations typically contain a minimum of about 8 different ingredients and some may contain 20 or more ingredients. Combining a number of individual ingredients into a homogenous product can create challenges to get ingredients to disperse, go into solution, and mix. In addition, the finished consumer product formulation itself must have appropriate chemical and microbiological stability to assure product performance and safety for the intended life of the product. As a result, acids and bases are commonly added to the formulations to change the chemical state of organic acids and bases in the formulation to maximize the incorporation of individual ingredients and to maximize finished product integrity. Citric acid may become sodium citrate in the product. Benzoic acid may become sodium benzoate. Sodium ascorbate may become ascorbic acid. Almost every consumer product formulation employs acid-base chemistry as an integral part of product formulation. This concept is so fundamental and so pervasive in product formulation that many manufacturers may not even realize this is a chemical reaction that could be subject to the CWC.

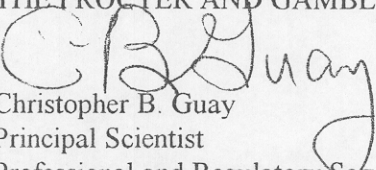
Since the objective of consumer product manufacturing is formulating a finished product for packaging and consumer use, manufacturers focus finished product testing on those parameters most critical to confirming product performance, stability and safety. For a manufacturer, finished product pH is usually a more important indicator than quantifying how much sodium citrate was formed during formulation. As a result, the amount of product formed is typically not measured.

We recommend that acid-base reactions conducted as part of consumer product formulation be exempted from CWC reporting and inspection requirements. This type of reaction is pervasive in product formulation, is formulation specific, and is not currently quantified by most manufacturers. Quantifying this type of reaction would be technically difficult, costly and provide little information pertinent to the scope and objectives of the CWC.

If you have any further questions regarding this submission, please contact me at (513) 627-6016 [phone] , (513) 627-6086 [fax], or at guay.cb@pg.com [e-mail].

Sincerely,

THE PROCTER AND GAMBLE COMPANY

  
Christopher B. Guay  
Principal Scientist  
Professional and Regulatory Services



# The Goodyear Tire & Rubber Company

Akron, Ohio 44316-0001

January 31, 2000

Regulatory Policy Division  
Office of Exporter Services  
Bureau of Export Administration  
Room 2705  
14<sup>th</sup> Street and Pennsylvania Avenue, NW  
Washington, DC 20230

Re: Comments of The Goodyear Tire & Rubber Company on Interim Rule,  
Chemical Weapons Convention Regulations (CWCR), 64 Federal Register  
73743-73817 (December 30, 1999)

Dear Sir or Madam:

Attached hereto as Exhibit A is a copy of a presentation slide captioned "Industry Rights," "Declared Plants" that was prepared by the U.S. Arms Control and Disarmament Agency (USACDA) and was presented to industry in 1993. In this presentation slide, USACDA represented to industry that:

- a) A "Declared Plant" was a subset of a "plant site," and
- b) That one of the "rights" that "industry" would have is the right to exclude R&D labs, pilot plants, and "non-relevant production units" from inspection.

The Interim Rule is ambiguous and fails to expressly and clearly incorporate the above "rights." The Interim Rule:

- a) Fails to expressly incorporate the following language in the Chemical Weapons Convention Implementation Act (CWCIA):

"The owner or the operator, occupant, or agent in charge of the premises to be inspected may withhold consent for any reason or no reason." [22 USC 6725(a)]

- b) Provides that "When an owner, occupant, or agent in charge of a facility consents to an initial or routine inspection, he or she is consenting to provide access to the Inspection Team and Host Team to any area of the facility, any item located on the facility, interviews with facility personnel, and any records necessary for the Inspection Team to complete its mission...The determination of whether the Inspection Team's request to inspect any area, building, item or record is reasonable is the responsibility of the Host Team Leader." [Section 716.4(2)] (Emphasis added)
- c) Provides that "The Inspection Team may visually inspect the declared plant or facility and other areas of the plant site or facility as agreed by the Host Team Leader after consulting with the facility representative." (Section 716.4) (Emphasis added)

The above sections should be amended to expressly state consistent with the CWCIA and the representations of the USACDA that:

- a) The owner or the operator, occupant, or agent in charge of the premises to be inspected may withhold consent to an inspection for any reason or no reason;
- b) When an owner, occupant or agent in charge of the premises consents to an initial or routine inspection, he or she is not consenting to provide access to, and has the right to deny access to:
  - 1) R&D labs
  - 2) Pilot plants
  - 3) Non-relevant production units, including, but not limited to:
    - i) Plants and production units that are exempted from UDOC declaration requirements (including but not limited to plants and production units producing polymers and oligomers consisting of two or more repeating units which are formed by the chemical reaction of monomeric or polymeric substances).
    - ii) Plants and production units producing chemicals by fermentation, extraction, purification, distillation, and/or filtration.

The Interim Rule should further be amended to state that the owner, occupant, or agent in charge of the premises to be inspected may withdraw consent at any time and that withdrawal of consent will not be a violation under §719.2(a)(1) of the CWCR (as stated in the preamble at page 73755).



The Interim Rule should further be amended to expressly state, as provided in the CWCIA, that no inspection shall extend to:

- (A) financial data;
- (B) sales and marketing data;
- (C) pricing data;
- (D) personnel data;
- (E) research data;
- (F) patent data;
- (G) data maintained for compliance with environmental or occupational health and safety regulations; or
- (H) personnel and vehicles entering and personnel and personal passenger vehicles exiting the facility. [22 USC §6724(e)(2)].

Section 718.1 of the Interim Rule improperly narrows the definition of Confidential Business Information set forth in the CWCIA. Section 103(g) of the CWCIA defines "Confidential Business Information" to mean:

"any trade secrets or commercial or financial information that is privileged and confidential –

- (1) including –
  - (A) data described in section 6724(e)(2) of this title,
  - (B) any chemical structure,
  - (C) any plant design process, technology, or operating method,
  - (D) any operating requirement, input, or result that identifies any type or quantity of chemicals used, processed, or produced, or
  - (E) any commercial sale, shipment, or use of a chemical, or
- (2) as described in section 552(b)(4) of Title 5 [22 USC §6713(g)]  
(Emphasis added)

The exemption in Section 552(b)(4) of the Freedom of Information Act states:

"(b) This section does not apply to matters that are –

....

- (4) trade secrets and commercial or financial information obtained from a person and privileged or confidential."

The definition of Confidential Business Information in the CWCIA is not limited to the categories set forth in Section 718.1 of the Interim Rule. It covers "any trade secrets or commercial or financial information that is privileged and confidential." It not only covers "trade secrets" under 5 USC 552(b)(4), it covers "commercial or financial information obtained from a person and privileged or confidential" under 5 USC 552(b)(4). The scope of the protection afforded to "trade secrets and commercial or financial information obtained from

a person and privileged or confidential” is very broad [See e.g. A Review of the Fourth Exemption of the Freedom of Information Act, 9 Akron L. Rev. 673 (1976)] The definition of Confidential Business Information in Section 718.1 of the Interim Rule must, therefore, be revised to conform to the much broader definition of Confidential Business Information set forth in the CWCIA.

Respectfully submitted,

*Ronald P. Yaist* HTR

Ronald P. Yaist  
Director, Patent & Trademark Department

/plt

Attachment





# INDUSTRY RIGHTS

## DECLARED PLANTS

- Sub-Set of Facility/Plant-Site
- Production Unit/Waste Stream/Storage/Controls/Records
- Other Site Elements Which May Be Excluded from Inspection
  - R&D Labs
  - Pilot Plants
  - Non-Relevant Production Units



## FACILITY AGREEMENTS FOR ROUTINE INSPECTIONS

- Negotiated during first visit to plant
- Industry to Government/OPCW
- Limit scope of inspection
- Define special procedures



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CHEMICAL MANUFACTURERS ASSOCIATION

KATHLEEN A. AMBROSE  
VICE PRESIDENT  
INTERNATIONAL AFFAIRS

January 31, 2000

Regulatory Policy Division  
Office of Exporter Services  
Bureau of Export Administration, Room 2705  
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14<sup>th</sup> Street and Pennsylvania Avenue, N.W.  
Washington, D.C. 20230

Re: Comments on the U.S. Department of Commerce's Interim Rule Regarding the Chemical Weapons Convention and the Chemical Weapons Convention Implementation Act of 1998

To Whom It May Concern:

The Chemical Manufacturers Association (CMA) is pleased to provide the Department of Commerce with the following comments and suggestions on its interim rule implementing the Chemical Weapons Convention (CWC) and the Chemical Weapons Convention Implementation Act (CWCIA). 64 Fed. Reg. 73,744 (December 30, 1999).

As you know, the CMA is a non-profit trade association whose 190 member companies represent 90 percent of the productive capacity for basic industrial chemicals in the United States. On August 20, 1999, CMA submitted extensive comments on the proposed Chemical Weapons Convention Regulations (CWCR), published on July 21, 1999.\* The interim final rule reflects BXA's awareness and appreciation of industry interests in the context of the CWC. CMA and its member companies have long supported full implementation of the CWC, and we make these additional comments to address concerns over specific requirements of the interim final rule.

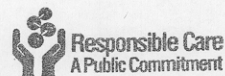
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\* Please see Comments of the Chemical Manufacturers Association on BXA's Proposed Rule Regarding the Chemical Weapons Convention Regulations (CWCR), 64 Fed. Reg. 39,193 (July 21, 1999), Docket No. 990611158-9158-01, submitted on August 20, 1999; CMA's Comments on the U.S. Department of State's Proposed Rule Regarding the Chemical Weapons Convention and the Chemical Weapons Convention Implementation Act of 1998; Taking of Samples; Record Keeping and Inspections, 64 Fed. Reg. 39,244 (July 21, 1999), submitted on August 20, 1999; and CMA's Comments on the Chemical Weapons Convention Declaration Forms pursuant to the Department of Commerce's Notice of Office of Management and Budget (OMB) Review and Request for Comments, 64 Fed. Reg. 39,969 (July 23, 1999), submitted on August 20, 1999.



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### **Section 713.3 – Initial and Annual Declaration Requirements for Schedule 2 Plant Sites**

CMA is unclear on the requirements for annual declarations on past activities involving Schedule 2 chemicals. Specifically, the note to Section 713.3 paragraph (a) (1) (ii) creates confusion by basing the annual declaration requirement on three years of activity.

Neither the CWC nor CWCIA require annual declarations from Schedule 2 facilities on other than above-threshold activities that occurred in 1997, 1998 and/or 1999. Above-threshold production, processing and/or consumption of Schedule 2 chemicals in any or all of these years triggers an annual declaration requirement. BXA's interpretation of treaty requirements, as reflected in the note conflicts with the CWC and CWCIA's dictated timeframe for annual declarations and the clear correspondence of annual declaration with a single year, not series of years.

Furthermore, Section 401 of the Act commits the U.S. government to require only the minimal information necessary to satisfy the requirements of the Convention and Act. CMA believes the requirement to reflect three years of data in annual declarations is unnecessary. The CWC allows the Organization for the Prohibition of Chemical Weapons' (OPCW) to request additional data on declared activities during on-site inspections and a single year's worth of data should suffice to demonstrate U.S. compliance with the CWC. CMA urges BXA against such an excessive interpretation of the treaty that defeats BXA's conscientious and demonstrated efforts to minimize the burden on industry.

CMA suggests BXA clarify the requirement for submission of an annual declaration of above-threshold Schedule 2 activities for any and/or all of the years 1997, 1998 or 1999, as applicable.

### **Section 715.1 – Initial and Annual Declaration Requirements for Discrete Organic Chemicals**

CMA supports the exemption from CWC reporting requirements for Unscheduled Discrete Organic Chemicals (UDOCs) produced by synthesis that are ingredients or by-products in foods designed for consumption by humans and/or animals. CMA interprets this exemption to include dietary supplements.

Under Section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 321 (FF), a dietary supplement means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these ingredients. According to the Act, a dietary supplement is a food.

CMA encourages BXA to reference the FFDCA in interpreting Section 715.1 (E) to exempt dietary supplements from UDOC reporting requirements as ingredients in foods designed for consumption by humans and/or animals.

Further to UDOC reporting, CMA offers the following input in response to the Department of Commerce's request for public comment on the impact of the CWCR on facilities that produce UDOCs solely as consumer goods packaged for retail sale. CMA recommends that BXA exempt two additional types of facilities and in particular, facilities that process edible oils and edible oil byproducts solely for use in packaged consumer goods other than those intended for consumption by humans or animals and, facilities that produce detergents solely for packaged consumer goods.

Edible oils are complex mixtures of various constituents. The performance of many consumer products including, soaps, shampoos, and personal care products is based on a collection of edible oils so these mixtures are not typically separated or analyzed for use. The concentration, distribution and reaction of these constituents vary from lot to lot. If applicable, the DOC reporting requirement would result in an unnecessary and costly analysis of mixtures made in-house expressly for incorporation into consumer products. Given the circumstances surrounding edible oils processing and the noticeable absence of any direct threat to the object and purpose of the convention, CMA recommends that BXA adopt an exemption for facilities involved exclusively in the processing of indiscrete edible oils for use in packaged consumer products. CMA argues in favor of a similar exemption for facilities involved in the production of detergents solely for packaged consumer goods.

#### **Section 712.6, 713.7 and 714.6 – Amended Declarations**

The interim rule requires that Schedule 1, 2, or 3 sites subject to inspection submit an amended declaration to the Department of Commerce announcing changes in previously submitted information, including a change in company name. CMA questions the need for such sites to submit an amended declaration in the event of a mere change in company name.

CMA recognizes that changes to declared products and processes involving CWC chemicals directly impact on-site verification activities. CMA also recognizes that chemical manufacturing is as global as trade itself. The supply and customer chains span states and even continents. For functional, operational and financial reasons, companies regularly undertake technical reorganizations. These changes may result in the incorporation of separately named subsidiaries or divisions into the same parent company.

A change in company name is not substantive and has no impact on CWC verification activities, the object and purpose of the CWC and/or plant site identification code. Declarable facilities are assigned a unique identification code and name changes can be made through subsequent annual declarations. Given the routine changes in company names within the industry, CMA believes that requiring amended declarations for name changes results in a paperwork burden that makes no meaningful contribution to national compliance. CMA requests that Commerce eliminate the requirement for an amended declaration on a change in company name.



## **Section 721.1 - Record Keeping**

CMA remains concerned over the interim final rule's record keeping requirements. CMA acknowledges BXA's revision of the requirements to obligate maintenance of only records that support declarations, reports, or notifications submitted under the CWCR rather than all records that somehow pertain to the CWCR. However, CMA believes the requirements continue to compete with industry's efforts to practice economic and efficient record management.

CMA understands that companies' record management programs are unique to their respective product lines, commercial and customer networks, regulatory responsibilities and various record retention policies. Companies' constantly strive to perfect record management practices for compliance and competitive purposes. The CWCR's overly strict record keeping requirements will compound the costs of record keeping by possibly forcing the reorganization of record management centers and physical relocation of stored records.

CMA reiterates its request to allow the maintenance of duplicates of originals for purposes of complying with the CWC. Business is routinely and reliably conducted using reproductions of original records and federal and state laws do not discriminate against duplicate records. CMA also encourages BXA to allow for the use of any form of reproduction such as microfilm, computer tape or photocopy as well as permit the disposal of records provided in response to an agency request. As regards the physical location of records, CMA encourages BXA to grant inspectable and non-inspectable facilities the freedom to maintain records on-site and/or at locations convenient to the facility. CMA appeals to BXA to relax the record keeping requirements in recognition of industry's demonstrated commitment to full compliance and in the interest of avoiding costs to and interruptions of ordinary business.

## **CWC Declaration Forms**

CMA is pleased with the CWC Declaration and Report Handbooks for Schedule 1, 2, 3, and UDOCs completed on December 30, 1999. CMA commends BXA for improving the individual handbooks' organization and clarity. At the same time, CMA encourages BXA to allow still another possible means of determining the latitude and longitude of a declarable plant site and namely, LandView III Mapping Software. CMA understands that various industries already rely on this software for such determinations and suggests BXA allow the use of this and similar software in the course of CWC inspections as a means to further minimize the CWC's compliance costs to industry.

## **Conclusions**

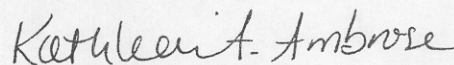
CMA appreciates BXA's publication of thoughtful and thorough responses to public comments on the proposed CWCR. CMA is particularly pleased with BXA's adoption of practical approaches to CWC implementation including:

- Consolidation of the provisions on Confidential Business Information (CBI);

- Extended timeframe for the submission of annual declarations and reports on additionally planned activities;
- Acceptance of industry's best efforts to report on past activities;
- Assurance of consultation with industry on critical issues including, CBI;
- Adoption of a 30% rule on Schedule 2 low concentrations and .5% rounding rule on Schedule 1 chemicals;
- Expansion of the exemptions from UDOC reporting for refineries and food ingredients; and
- Incorporation of a glossary of terms and provision for the electronic submission of inquiries on covered chemicals and binding determinations on chemicals subject to the CWC.

CMA is grateful for the continued open exchange of information and ideas with the Department of Commerce on CWC implementation. CMA looks forward to future opportunities to share its perspective and expertise in an effort to improve the CWC declaration and inspection system. If you have any questions about CMA's comments, please contact me at 703/741-5920 or Marybeth Kelliher of my staff at 703/741-5923.

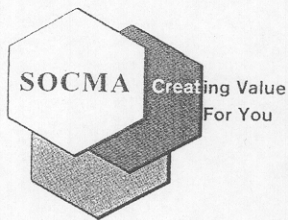
Sincerely,



Kathleen A. Ambrose  
Vice President, International Affairs

cc: Steven Goldman, Department of Commerce  
Bob Mikulak, Department of State  
Charlotte Gallagher, Federal Bureau of Investigation





SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, INC.  
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January 31, 2000

Regulatory Policy Division  
Office of Exporter Services  
Bureau of Export Administration  
Room 2705  
14th Street and Pennsylvania Avenue, N.W.  
Washington, D.C. 20230

Re: Comments on the U.S. Department of Commerce's Interim Rule Regarding the Chemical Weapons Convention (CWC) and the Chemical Weapons Convention Implementation Act of 1998 (CWCIA)

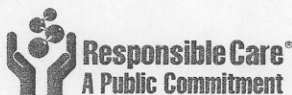
To Whom It May Concern:

The Synthetic Organic Chemical Manufacturers Association (SOCMA) is pleased to provide the Department of Commerce Bureau of Export Administration (BXA) with the following comments and suggestions on the Chemical Weapons Convention Regulations (CWCRC), 64 Fed. Reg. 73744 (December 30, 1999), Interim rule and request for comments.

SOCMA is the leading trade association representing the batch and custom chemical industry. SOCMA's 300+ member companies make the products and refine the raw materials that make our standard of living possible. From pharmaceuticals to cosmetics, soaps to plastics and all types of industrial and construction products, SOCMA members make materials that save lives, make our food supply safe and abundant, and enable the manufacture of literally thousands of other products.

The most significant factor distinguishing companies in the chemical industry is the type of production. Chemicals are manufactured using one of two distinct methods: batch or continuous. A continuous operation utilizes a constant raw material feed to the process vessel and continual product withdrawal. Continuous manufacturing provides the most efficient means to manufacture large volumes of single chemicals. Typically, large chemical manufacturers utilize continuous processes since most have non-diverse product lines.

By contrast, a batch process involves the intermittent introduction of frequently changing raw materials, varying process conditions within the vessel, and different removal methods.



Batch processors make small quantities of chemicals to meet specific needs and consumer demands for specialized products including specialty, custom, and fine chemicals. Custom chemical production is highly competitive, in both the domestic and international arenas, often with relatively lower profit margins.

Because of the specialized nature of the custom and specialty chemical manufacturing business, batch chemical facilities are typically small, averaging fewer than 1000 employees. On the other hand, commodity chemical manufacturing companies tend to be large, with 2500 or more employees. Most SOCMA member companies use batch manufacturing for their products and employ fewer than 500 people.

SOCMA is appreciative of the Department of Commerce's consideration of SOCMA's comments on the proposed rule for the implementation of the CWC and the CWCIA. SOCMA requests careful consideration of the following comments on the interim rule and the Declaration and Report Handbooks.

#### **Part 711 – General Information Regarding Declaration, Reporting and Notification Requirements**

SOCMA has received several requests from member companies regarding the address for submittal of declaration forms and reports. It is SOCMA's understanding that the declaration forms and reports are to be returned to the Information Technology Team located in Arlington, Virginia. Neither the regulations nor the declaration and report handbooks address this question.

SOCMA suggests that a new section (711.7) be added to the final rule to specify the department and address for submittal of completed declarations and reports. Additionally, each declaration and report handbook should provide the same information in the "Introduction" section. To make it easier for companies to comply, SOCMA would additionally recommend that each declaration and report form contain the information on where it should be submitted.

#### **Part 712.6, 713.7 and 714.6 – Amended Declarations**

SOCMA understands that Schedule 1, 2, or 3 sites that are subject to inspection are required to submit an amended declaration to the Department of Commerce announcing changes in previously submitted information on chemicals, activities and end-use purposes or the addition of new chemicals, activities, and end-use purposes. Changes to declared products and processes involving CWC chemicals have a direct impact on on-site verification activities.

SOCMA, however, questions the need for required sites to submit amended declarations of a change in company name. In today's global economy, chemical companies regularly undertake technical reorganizations for functional, operational and financial reasons. These changes may result in the incorporation of separately named subsidiaries or divisions incorporated into the same parent company. These changes have become routine within the chemical industry.



Given that a change in company name is non-substantive and has no impact on CWC verification activities, the object or purpose of the CWC, or the plant site identification code, SOCMA objects to the requirement for submission of an amended declaration to report this change. SOCMA believes that this requirement increases the paperwork burden, especially for small companies that have limited resources and personnel. Moreover, SOCMA questions the benefits of this requirement for the purposes of national compliance. Therefore, SOCMA requests that the Department of Commerce eliminate the requirement for an amended declaration on a change in company name.

Second, SOCMA requests that the Department of Commerce provide deadlines for submission of amended declarations. Currently, the regulation only requires that companies submit amended declarations. Given that the declarations are important for accurate on-site verification, SOCMA believes that the Department of Commerce should clearly provide companies with guidance on a reasonable timeframe for submittal of the amendments. SOCMA believes that amendments should be submitted within 90 days of the event that triggered a requirement for an amended declaration. SOCMA believes that 90 days is appropriate as that is the same amount of time given for annual declarations following the close of a calendar year.

### **Section 713.3 – Initial and Annual Declaration Requirements for Schedule 2 Plant Sites**

The interim rule is unclear on the requirements for annual declarations on past activities involving Schedule 2 chemicals. Specifically, the note to Section 713.3 paragraph (a) (1) (ii) creates confusion by basing the annual declaration requirement on three years of activity.

Neither the CWC nor CWCIA requires annual declarations from Schedule 2 facilities on other than above-threshold activities that occurred in 1997, 1998 and/or 1999. Above-threshold production, processing and/or consumption of Schedule 2 chemicals in any or all of these years triggers an “annual” declaration requirement. The note to Section 713.3 conflicts with the CWC and the CWCIA’s timeframe for annual declarations. Moreover, the CWCIA and CWC require annual declarations for a single year and not a series of years as presented in the note to Section 713.3 paragraph (a) (1) (ii).

Since Section 401 of the CWCIA commits the U.S. government to require only the minimal information necessary to satisfy the requirements of the CWC and the CWCIA, SOCMA believes that the collection of three years of data by those required to make annual declarations counters the intentions of the CWC. Therefore, SOCMA strongly opposes a three-year timeframe for purposes of reporting on annual activities and urges the Department of Commerce to clarify the requirements for separate annual declarations of above-threshold Schedule 2 activities for the years 1997, 1998 and 1999.

### **Section 715.1 – Initial and Annual Declaration Requirements for Discrete Organic Chemicals**

SOCMA interprets the exemption of Unscheduled Discrete Organic Chemicals (UDOCs)

produced by synthesis that are ingredients or by-products in foods designed for consumption by humans and/or animals to exclude dietary supplements such as neutraceuticals from CWC reporting requirements.

Neutraceuticals are an increasingly common dietary supplement found in nature or produced by chemical synthesis. Under Section 201 of the Federal Food, Drug and Cosmetic Act (FFDCA), Pub. L. No. 75-75-717 Stat. 1040 (1938), a dietary supplement means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these ingredients. According to the Act, a dietary supplement is a food.

SOCMA encourages BXA to reference the FFDCA in interpreting Section 715.1(a)(2)(E) to exempt neutraceuticals from UDOCs reporting as ingredients in foods designed for consumption by humans and/or animals.

### **Section 718.1 – Confidential Business Information Definitions**

In Section 718.1 (h), SOCMA notes a reference to “personnel passenger vehicles” (page 73803). The term used in the CWC Verification Annex is “personal passenger vehicles”. The CWCR should be changed to reflect the terminology used in the CWC.

### **Miscellaneous Comments on the CWCR**

It is SOCMA’s understanding that the Organization for the Prohibition of Chemical Weapons (OPCW) recently amended the requirements relating to transfers of Saxitoxin. SOCMA recommends that the Department of Commerce incorporate the changes into all parts of the regulation that relate to the reporting of Saxitoxin transfers. In addition, the Handbook for Schedule 1 Declarations and Reports also should be amended to reflect these changes. Furthermore, SOCMA believes that upon any such amendments by the OPCW, BXA should initiate notice and comment rulemaking to change the CWRC where it does not conflict with the CWCIA.

### **Miscellaneous Comments on the CWC Declaration and Report Handbooks**

SOCMA is pleased with the CWC Declaration and Report Handbooks for Schedule 1, 2, 3, and UDOCs completed on December 30, 1999. In particular, SOCMA commends the Department for compiling a glossary of terms and providing it with each handbook. SOCMA believes that the individual handbooks’ organization and clarity have been greatly improved. At the same time, SOCMA has three additional comments that would make a company’s use of the handbooks more efficient.

First, as mentioned previously, SOCMA believes that the address for submittal of declaration forms and reports must be clarified for reporting companies. SOCMA suggests that



the Introduction to each notebook address this issue. In addition, SOCMA believes that the best way to provide this information to reporting companies is to include it on each report or declaration form.

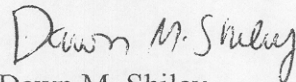
Second, SOCMA understands that the CWCR requires companies to submit an advanced notice of schedule 1 imports or exports. This notification is to be submitted on company letterhead and not on a specified form. SOCMA believes that the declaration and report handbook for Schedule 1 Chemicals should include an explanation of this requirement. No additional form is necessary. A clarifying statement in the Handbook on page 9 and the bottom of page 11 should provide the companies with a clearer understanding of the requirement.

Lastly, Supplement 1 to each of the Forms packages contains a detailed explanation of how to determine facility latitude and longitude. SOCMA is appreciative that multiple suggestions on how to complete this task, including the use of Global Positioning Systems (GPS). SOCMA suggests that an additional resource be included in the list of ways to determine latitude and longitude. Many companies use LandView® III software which includes census data to determine their location for other regulations. In the current forms handbooks, there is a mention of census data. SOCMA believes that this section should also include a mention of the software and indicate that additional information is available about this from the U.S. Census Bureau or by visiting [www.census.gov/geo/www/tiger/index.html](http://www.census.gov/geo/www/tiger/index.html) on the Internet.

## Conclusions

SOCMA appreciates the opportunity to submit these comments and requests that they be accorded careful consideration. SOCMA is willing to examine and comment on any additional forms that BXA contemplates for the implementation of the CWCR. Should you wish to discuss these comments or any other CWC issues, please contact me at (202) 721-4137.

Sincerely,



Dawn M. Shiley *ms4*

Director

Public, Congressional & International Affairs